REMARKS

Applicant respectfully requests entry of the amendments and remarks submitted herein. Claim 1 has been amended to incorporate the limitation of claim 27, and claims 27 and 28 have been cancelled. The claims as amended are allowable, or in the alternative, the amendments place the claims in better condition for appeal. Reconsideration of the pending application is respectfully requested.

Applicant notes that a Supplemental Response was filed with the U.S. Patent and Trademark Office on August 22, 2003, which contained the same amendment that is being made herein. The Supplemental Response of August 22, 2003 was not entered by the Examiner, and a Final Office Action was mailed on August 25, 2003. Applicant submits that under MPEP §714.05, the Examiner should have entered Applicant's amendment and reissued a new Office Action. In addition, the Examiner did not provide any reason under MPEP §714.19 or otherwise for not entering the August 22, 2003 amendment.

The 35 U.S.C. §103 Rejections

Claims 1, 4, 7-9, 27, and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sugitachi et al., Fischer et al. or DE 3007226 taken with WO 92/14480 and Poelstra et al. and further in view of Millan et al. This rejection is respectfully traversed.

Without acquiescing to the Examiner's rejection, Applicant has herein amended claim 1 to recite that the claimed composition is formulated for topical delivery. Claim 1 as amended is not obvious over the cited art for the following reasons.

The Examiner asserted that gelatin, insulin, and alkaline phosphatase have been shown individually to treat wounds and therefore, that it would be obvious to use the same components in a single composition for the same purpose. Applicants strongly disagree with the Examiner's assertion.

The Sugitachi et al. reference discloses that Factor XIII with or without thrombin can be attached to a structure such as a gelatin sponge and applied to a wound site. The Fischer et al. reference discloses a bandage composition that, in addition to other components, can contain a gel or agarose component. The DE 3007226 reference discloses that chlorhexidine and allantoin

incorporated into gelatin capsules can exert a synergistic effect on healing. The WO 92/14480 reference discloses administering recombinant G-CSF or GM-CSF to accelerate wound healing. The Poelstra et al. reference discloses that alkaline phosphatases have endotoxin-detoxifying activity and can therefore be used to treat or prevent complications due to Gram-negative bacterial infections. The Millan et al. reference teaches the biology of human alkaline phosphatases. Applicant respectfully directs the Examiner to the Response of June 5, 2003 for a more complete discussion of the cited art.

None of the cited references teach or suggest that placental alkaline phosphatase can be used topically to stimulate production of skin fibroblasts and treat wounds. The only reference the Examiner has provided that discloses using placental alkaline phosphatase is the Poelstra et al. reference, which discloses that placental alkaline phosphatases can be used systemically to prevent sepsis caused by a Gram-negative bacterial infection. This disclosed use of placental alkaline phosphatase does not make obvious Applicant's claim 1 as amended.

In addition, the ability of placental alkaline phosphatase to stimulate production of skin fibroblasts is unexpected. "In the present approaches, contrary to earlier work, it has been discovered that PALP...stimulate[s] proliferation of adult fibroblasts, in particular adult skin fibroblasts" (see the sentence bridging pages 5 and 6 of the specification).

Therefore, the cited art, either alone or in combination, does not teach or suggest using *placental* alkaline phosphatase formulated for *topical* delivery in an amount effective to *stimulate proliferation of fibroblasts* to treat *skin* wounds. In view of the amendments and remarks herein, Applicant respectfully requests that the rejection of claims 1, 4, 7-9, 27, and 31 under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicant respectfully requests that claims 1, 4, 7-9, and 31 be allowed.

In addition, claims 3, 5, 6, 10, 29, and 30 were withdrawn as directed to a non-elected species following the Restriction Requirement of November 5, 2002 and Applicant's election of December 5, 2002. Since claim 1 as amended should be allowable, Applicant respectfully requests that claims 3, 5, 6, 10, 29, and 30 be rejoined and allowed pursuant to MPEP §809.02(c)(B)(1).

Further, Applicant requests that the Examiner consider rejoining the claims directed to an article of manufacture containing the composition of claim 1 (essentially corresponding to cancelled claims 32-35). According to the TC1600 Restriction Practice Action Plan (copy enclosed), the U.S. Patent and Trademark Office will publish claim sets that will be examined together regardless of whether they can otherwise be restricted under 35 U.S.C. §121 because the search and examination of the claims do not present a serious burden on the Office. Applicant submits that the claims directed toward articles of manufacture containing the composition recited in amended claim 1 are an example of claims that do not present an additional search burden on the Examiner. Applicant submits that these claims should be entitled to rejoinder. If the Examiner agrees, Applicant hereby authorizes the Examiner to add article of manufacture claims by an Examiner's amendment.

Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: November 21, 2003

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